

EPA Responses to interagency Comments Received from OMB and SBA by phone  
12/19/19

January 15, 2020

EPA RESPONSE 3\_RIN2070-AJ99\_EO12866\_LCPFAC-PFAS-SNUR\_2020-01-15.docx

COMMENTS ON THE SUPPLEMENTAL NOTICE OF PROPOSED RULEMAKING

**1. EPA Change:** EPA will be changing the public comment period from 60 days to 45 days. This adjustment is necessary in order to comply with deadlines established by the National Defense Authorization Act for Fiscal Year 2020. The Act reads, "Not later than June 22, 2020, the Administrator shall take final action on the proposed rule entitled ``Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule" (80 Fed. Reg. 2885 (January 21, 2015))."

**2. EPA Change:** As a follow-up to previous interagency comments, EPA opposes establishing a threshold for a "reasonable potential for exposure" that "justifies notification" but has agreed to include a request for comment on establishing a threshold (in green below). Additionally, EPA opposes proposing a "safe harbor" provision, but is open to a neutrally-worded request for comment (in blue below). EPA will add the following at line 204:

EPA also requests comment on whether or not the Agency should establish a threshold at which a significant new use exhibits reasonable potential for exposure that justifies notification. While TSCA section 5(a)(5) does not establish a threshold and does not require EPA to establish a threshold, EPA may establish a threshold if appropriate. Additionally, EPA requests comment on whether or not the Agency should include a safe harbor provision for importers of articles that can demonstrate the use was ongoing prior to the effective date of the rule. EPA requests that commenters provide support either for or against adding a safe harbor provision to this rule.

Summaries of comments received by phone on 12/19/19 and EPA's responses follow the original incoming and passback comments

**COMMENT 1:** Reviewers are aware of the complexities and burden on EPA to establish that a given use of a chemical is no longer in use for articles in US commerce. Given the complex nature of tracking chemicals in articles as part of an end product on the market, particularly for this SNUR, we strongly recommend and encourage EPA adding a safe harbor provision for importers of articles that can demonstrate the use was ongoing prior the effective date (date of the proposal) if those uses were missed (not identified) during the rulemaking process and not included in the final SNUR. EPA acknowledges difficulties in complying that are likely as a result of long and diverse supply chains and should consider providing an assurance for good-faith actors who might otherwise violate the law on technicalities beyond their reasonable control. We would like to note that a safe harbor provision is not new to US regulations or even statutes, so proposing a safe harbor provision would not be precedent setting, but rather, the exclusion of providing that could be considered precedent setting. Nothing in TSCA or its

amendments prevents EPA from providing it in this case. In addition to adding a safe harbor provision, we would further recommend EPA solicit comment on this provision.

**EPA Response:** EPA makes every effort to notify manufacturers and processors of chemical substances that may be subject to a given rule, so that they may participate in the regulatory processes. EPA does not believe there should be a safe-harbor provision in the rule for uses not included in the SNUR. A safe-harbor provision provides incentives for importers to not submit comments to EPA during the public comment information on ongoing uses not recognized in a proposed rule. EPA also notes that the Agency's general SNUR regulations contain an exemption for a person who "manufactures, imports, or processes the substance only as an impurity." 40 CFR 721.45(d). An impurity is "a chemical substance which is unintentionally present with another chemical substance." 40 CFR 720.3(m) (which applies pursuant to 40 CFR 721.3). Additionally, EPA notes that the scenario described in the comment would not necessarily exclude the importer of articles from doing so permanently; rather, it would require the importer to submit a Significant New Use Notice (SNUN), undergo EPA review and determination of potential risks associated with the significant new use, and comply with any action associated with EPA's determination.

**Follow-up Comment 1:** Agreed that a safe-harbor provision should not be provided for uses not included in the SNUR. The safe-harbor provision is requested for those uses that would be considered ongoing because they were in fact ongoing at the time of the proposal but not necessarily known or identified as such during the comment period process. Not sure why an importer would knowingly not take advantage of an opportunity to note its ongoing use of a chemical so that it does not have to pay the SNUN fee. Can EPA elaborate as to why it believes that importers would be incentivized to not note their ongoing uses?

The impurity exception is useful and seems necessary but it is meant to apply to an unintentional presence of a chemical rather than an ongoing but unknown import of a chemical as part of an article.

Once again, the scenario described in the comment is not meant to exclude anyone from reporting, instead, it is meant to provide importers of articles with ongoing use (that were not identified during public comment) a chance to demonstrate that their use was ongoing prior to the effective date so that they do not have to incur the cost of a SNUN.

In addition, we strongly urge the agency to reconsider this provision. EPA has acknowledge and recognized that there are many instances, due to a lack of knowledge (through complete information from manufacture to final product) in the supply chain, of what chemicals are in final products, especially those that are complex items. It is therefore foreseeable that importers may not be aware of the chemicals that are in surface coatings of products subject to this rule.

**EPA Follow-up Response:** EPA appreciates the comment but maintains that a safe-harbor provision is not appropriate for this rule. While EPA acknowledges that imported articles may have a complex supply chain, the most effective method to ensure that the LCPFAC chemical substances in this SNUR are not present in imported articles is to encourage importers to know with specificity the contents of what they are importing and to work with their foreign manufacturers to ensure that an article does not contain certain LCPFAC chemical substances.



EPA provided notice to importers in the 2015 proposed rule and will again provide notice of the proposed requirements in this supplemental proposal. A safe harbor approach undermines clarity for what uses are allowed and thus raises fair notice issues in the context of compliance monitoring. EPA believes a safe-harbor provision would enable importers to remain ignorant of the contents of imported articles if an importer is able to claim that they were unaware that the article contained a substance subject to a rule.

**December 19, 2019 Call - Follow-up Comment 1:** Reviewers asked that EPA request comment on whether EPA should include a safe-harbor provision in the final rule.

**EPA Follow-up Response:** EPA opposes proposing a “safe harbor” provision, but is open to a neutrally-worded request for comment (in blue below). In addition to the language adding a request for comment on the “reasonable potential for exposure” noted above (in green below), EPA will add the following at line 204:

EPA also requests comment on whether or not the Agency should establish a threshold at which a significant new use exhibits reasonable potential for exposure that justifies notification. While TSCA section 5(a)(5) does not establish a threshold and does not require EPA to establish a threshold, EPA may establish a threshold if appropriate. Additionally, EPA requests comment on whether or not the Agency should include a safe harbor provision for importers of articles that can demonstrate the use was ongoing prior to the effective date of the rule. EPA requests that commenters provide support either for or against adding a safe harbor provision to this rule.

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**COMMENT 75:** Page 27 (Economic Analysis). What is an approximate of this cost for a small business?

“compared to the cost of developing and marketing a chemical new to a firm or marketing a new use of the chemical”

**EPA Response:** Costs of developing and marketing a new chemical range depending on the industry and the market for the chemical. While EPA does not have an approximate cost of developing and marketing a new chemical for small businesses, it is assumed that these costs would be much higher than the estimated \$10,000 SNUN submission cost for small business submitters. EPA welcomes comment on any available estimates of these costs.

**Follow-up Comment 75:** Regarding the highlighted text, what is the basis for this assumption? Understood that the approximate cost is not known but does EPA have a range that supports this assumption?

**EPA Follow-up Response:** While EPA does not have estimates on the cost of developing and marketing a new chemical, one study released in 2006 by Cheminfo Services study (for Environment Canada) estimates a mean reformulation cost of \$31,700 and a maximum of \$114,000, which is well above the \$10,000 SNUN costs. The

costs of developing a new chemical would likely be much higher due to more extensive R&D, equipment and production, product testing, and marketing.

**December 19, 2019 Call - Follow-up Comment 75:** Reviewers asked that EPA add the follow-up response and the Cheminfo Services study to the Economic Analysis.

**EPA Follow-up Response:** EPA will add supporting text to the Economic Analysis section 6.1.:b

“Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency hereby certifies that promulgation of this SNUR will not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a significant new use. Where a use is new, by definition no small or large entities presently engage in such activities. Although some small entities may decide to manufacture or process a substance for the new use after the SNUR is promulgated, EPA receives very few SNUNs, and few of those are submitted by small entities. In response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of SNUNs per year. For example, the number of SNUNs received was 4 in Federal fiscal year (FY) 2005, 8 in FY2006, 6 in FY2007, 8 in FY2008, 7 in FY2009, 2 in FY2010, 10 in FY2011, 10 in FY2012, 11 in FY2013, 19 in FY2014, and 9 in FY2015 (EPA 2012), 1 for an average of between 8 and 9 per year from all SNURs. EPA has no reason to believe that this SNUR will alter the pattern of SNUN submissions that EPA has historically seen. In addition, the estimated reporting cost for submission of a SNUN is minimal regardless of the size of the firm, averaging about \$23,105 including SNUN recordkeeping and reporting costs. The Agency currently offers some relief to certain small businesses with average annual sales (including those of subsidiary/parent companies) of less than \$91 million in the three preceding years by reducing the SNUN submission fee from \$16,000 to \$2,800. This lower fee reduces the cost of submitting a SNUN to about \$9,905 for smaller firms. During the six year period from 2005 to 2010, only three submitters self-identified as small in their SNUN submission<sup>2</sup> (EPA 2012). EPA believes the cost of submitting a SNUN is relatively small compared the cost of developing and marketing a chemical new to a firm and that the requirement to submit a SNUN generally does not have a significant economic impact. While EPA does not have estimates on the cost of developing and marketing a new chemical, one study released in 2006 by Cheminfo Services study (for Environment Canada) estimates a mean reformulation cost of \$31,700 and a maximum of \$114,000, which is well above the \$10,000 SNUN costs (Cheminfo Services Inc. 2006). The costs of developing a new chemical would likely be much higher due to more extensive research and development, equipment and production, product testing, and marketing.

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**COMMENT 76:** Page 27 (Economic Analysis). What is the basis for this? Is the assumption that it will not cross the 1% threshold for any size group of any NAICS code identified?

“that the requirement to submit a SNUN generally does not have a significant economic impact.”

**EPA Response:** EPA believes the SNUR generally will not result in a significant economic impact. The estimated costs are \$23,000 per SNUN submission for large business submitters and about \$10,000 for small business submitters. It is important to point out that the costs are only incurred when a SNUN is submitted. The costs are relatively low. A one percent impact would only occur only for businesses below \$1 million in annual revenues. In terms of impact on a substantial number of entities, as noted on page 27, “EPA’s experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a small number of significant new use notices per year. During the six-year period from 2005-2010, only three submitters self-identified as small in their SNUN submission.” Based on this, EPA believes that few SNUN submissions will occur as a result of the rule.

**Follow-up Comment 76:** Regarding the highlighted text, are there any potential small businesses impacted by this rule with a revenue below \$1 million in annual revenues?

**EPA Follow-up Response:** EPA has no way of predicting which companies (if any) would submit a SNUN. The costs for the submitter would only occur if a SNUN is submitted. Based on historical data provided in our initial response to this comment and the fact that LCPFCs have been regulated globally and manufacturing phased out in the United States, EPA believes the number of SNUNs submitted will be very low.

**December 19, 2019 Call - Follow-up Comment 76:** To support EPA’s RFA analysis, reviewers asked that EPA add the following to the preamble: “Based on this, EPA believes that few SNUN submissions will occur as a result of the rule.”

**EPA Follow-up Response:** EPA will add the following at line 571 of the preamble:

...SNUN submission (Ref. 2). Based on this, EPA believes that few SNUN submissions will occur as a result of the rule.

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**EA COMMENT 1:** Please include a table in the RFA section with the average small revenue for the NAICS codes identified and the small entity cost as a percentage.

**EPA Response:** EPA agrees with the comment on adding a table in the RFA section of the Economic Analysis of average small business revenue for the affected NAICS codes. The table and accompanying text was added to Section 6.1, page 6-1 beginning at the second paragraph:

Exhibit 6-1 presents the average small business revenue for each 3-digit NAICS code represented by industries potentially affected by the rule. These average revenues are for illustrative purposes. It is not known how many firms will submit a SNUN and which

NAICS code they would comprise. EPA, therefore, cannot conclude whether any small businesses would have a significant impact as a result of this supplemental proposal.

<b>Exhibit 6-1: Average Small Business Revenue for Potentially Affected Entities</b>		
<b>NAICS</b>	<b>NAICS Description</b>	<b>Average Small Business Revenue (millions, 2018\$)<sup>1,2</sup></b>
315	Apparel Manufacturing	\$2.21
335	Electrical Equipment, Appliance, and Component Manufacturing	\$21.38
423	Merchant Wholesalers, Durable Goods	\$5.38
424	Merchant Wholesalers, Nondurable Goods	\$9.71
442	Furniture and Home Furnishings Stores	\$1.21
443	Electronics and Appliance Stores	\$1.05
444	Building Material and Garden Equipment and Supplies Dealers	\$1.72
448	Clothing and Clothing Accessories Stores	\$0.84
449	Sporting Goods, Hobby, Musical Instrument, and Book Stores	\$0.81
450	General Merchandise Stores	\$0.69
451	Non-store Retailers	\$1.60

**Source(s):**

U.S. Census Bureau (2015); U.S. Small Business Administration (2019); U.S. Bureau of Economic Analysis (2019)

**Note(s):**

<sup>1</sup> Revenues are inflated to 2018\$ using the Bureau of Economic Analysis Implicit Price Deflator for Gross Domestic Product

<sup>2</sup> Average small business revenues are estimated using the U.S. Census Statistics of U.S. Businesses (SUSB). The SUSB divides firms into revenue brackets according to the firm's annual receipts and employment size. To estimate revenues for just the small entities, average revenues were calculated only for the SUSB revenue or employment brackets where the upper bound is less than the SBA small business threshold. Note that this approach will result in a conservative estimate for small firm revenues, as it excludes the small firms with the largest revenues from the estimates.

**Follow-up EA Comment 1:** Regarding the highlighted text, in these statements, EPA appears to be stating that it does not know the small entity impact (or whether it would be substantial) and cannot know whether there is a significant impact. These two elements are crucial to establish a factual basis to be able to support an RFA certification.



**EPA Follow-up Response:** Similar to the response to comment #76 While EPA cannot predict the number of SNUNs submitted or by which type of companies. EPA believes the SNUR will not result in a significant economic impact. The estimated costs are \$23,000 per SNUN submission for large business submitters and about \$10,000 for small business submitters. It is important to point out that the costs are only incurred when a SNUN is submitted. The costs are relatively low. A one percent impact would only occur only for businesses below \$1 million in annual revenues. In terms of impact on a substantial number of entities, as noted on page 27, "EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a small number of significant new use notices per year. During the six-year period from 2005-2010, only three submitters self-identified as small in their SNUN submission." In addition, LCPFCs have been both regulated globally, and manufacturing has been phased out in the United States. Based on this, EPA believes that few SNUN submissions will occur as a result of the rule. Likely there would not be a substantial number of small businesses submitting SNUNs as a result of the Rule.

**December 19, 2019 Call - Follow-up EA Comment 1:** To support EPA's RFA analysis, reviewers asked that EPA remove "EPA, therefore, cannot conclude whether any small businesses would have a significant impact as a result of this supplemental proposal." and instead state "Based on this, EPA believes that few SNUN submissions will occur as a result of the rule."

**EPA Follow-up Response:** EPA agrees with the change. The accompanying text will be added to Section 6.1, page 6-1 beginning at the second paragraph of the Economic Analysis:

Exhibit 6-1 presents the average small business revenue for each 3-digit NAICS code represented by industries potentially affected by the rule. These average revenues are for illustrative purposes. It is not known how many firms will submit a SNUN and which NAICS code they would comprise. EPA, therefore, cannot conclude whether any small businesses would have a significant impact as a result of this supplemental proposal. Based on this, EPA believes that few SNUN submissions will occur as a result of the rule.